Complete Summary

GUIDELINE TITLE

Attention-deficit hyperactivity disorder.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Attention-deficit hyperactivity disorder. Ann Arbor (MI): University of Michigan Health System; 2005 Oct. 35 p. [8 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- <u>August 21, 2006, Dexedrine (dextroamphetamine sulfate)</u>: Changes to the BOXED WARNING, WARNINGS and PRECAUTIONS sections of the prescribing information.
- <u>September 29, 2005, Strattera (atomoxetine)</u>: Manufacturer asked to revise
 the prescribing information to include a boxed warning and additional warning
 statements that alert health care providers of an increased risk of suicidal
 thinking in children and adolescents.
- <u>August 2005</u>, <u>Adderall</u>: Return to Canadian market after February 2005 marketing suspension.
- October 15, 2004, Antidepressants: Public Health Advisory issued asking manufacturers of all antidepressant drugs to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Attention-deficit hyperactivity disorder (ADHD)

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Pediatrics

INTENDED USERS

Advanced Practice Nurses Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To recognize and treat attention-deficit hyperactivity disorder (ADHD) early in the primary care setting
- To identify appropriate treatment options and drug side effects
- To identify common comorbidities and indications for referral
- Identify appropriate support resources for patients and their families

TARGET POPULATION

Children aged 6 to 18 years with suspected or diagnosed attention deficit hyperactivity disorder (ADHD)

Note: Children aged 3 to 5 years and adults with suspected ADHD are also considered as "special populations."

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis and Evaluation

- 1. Assessment based on Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV criteria for attention-deficit hyperactivity disorder (ADHD)
- 2. Assessment using standardized rating scales for parent and teacher report (e.g., Child Behavior Checklist, Conners Rating Scales)
- 3. Standard history and physical examination
- 4. In-depth neurological examination
- 5. Assessment of co-occurring disorders

Management and Treatment

Pharmacotherapy

- 1. First-line
 - Stimulants (short-acting [immediate-release], intermediate-acting [sustained-/extended-release], long-acting [once-daily]) (methylphenidate, dexmethylphenidate, dextroamphetamine, mixed amphetamine salts)
 - Non-stimulants (Atomoxetine)
- 2. Second-line
 - Anti-depressants (bupropion, imipiramine, desipramine, nortriptyline)
 - Antihypertensives (clonidine, guanfacine)
 - Other drugs used to augment treatment (risperidone, trazodone)

Non-Pharmacological

- 1. Psychoeducation and support
- 2. Parent skills training
- 3. Family therapy
- 4. Attention deficit hyperactivity disorder (ADHD) support groups
- 5. Social skills training
- 6. Cognitive behavioral therapy
- 7. School consultations and interventions (intelligence testing, individualized education plan)
- 8. Alternative/complementary treatments

MAJOR OUTCOMES CONSIDERED

- Incidence of comorbid disorders
- Adverse effects of drug therapy
- Response to therapy
- Academic performance

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases The literature search for this guideline was conducted prospectively using the major keywords of attention deficit disorder with hyperactivity, human children age 3-18, English language, and published 1/1/99 to 9/30/02 on Medline. Additional key words were included clinical protocols, physician practice patterns, algorithms, consensus development conferences, practice guidelines, guidelines, outcomes and process assessment (health care); clinical trials, controlled clinical trials, multicenter studies, randomized controlled trials, cohort studies, metaanalysis or meta-analysis; costs and cost analysis; diagnosis, diagnostic use, sensitivity and specificity, false negative reactions, false positive reactions, likelihood functions, sensitivity, specificity; therapy, drug therapy, diet therapy, therapeutic use, rehabilitation.

The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was a single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consideration of benefits, harms, costs, and patient preferences

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership and in clinical conferences of departments to which the content is most relevant. Guidelines are approved by the Executive Committee of Clinical Affairs (ECCA). This guideline concerning attention deficit hyperactivity disorder (ADHD) was reviewed by members of the following clinical units: Behavioral Pediatrics, Child Psychiatry, Family Medicine, General Pediatrics, and Pharmacy Services.

The University of Michigan Health System Clinical Guideline on ADHD is consistent with the American Academy of Pediatrics Committee on Quality Improvement, Subcommittee on Attention-Deficit/Hyperactivity Disorder "Clinical Practice Guideline: Diagnosis and Evaluation of the Child With Attention-Deficit/Hyperactivity Disorder," 2000.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on diagnosis, treatment regimens, and costs.

Epidemiology

Common

Attention-deficit hyperactivity disorder (ADHD) is the most common behavioral disorder in school-age children. Studies demonstrate a U.S. community prevalence of 8 to 12%. It is more common in boys.

Primary Care Provider

Most children with ADHD will receive most or all of their care through primary care physicians.

<u>Diagnosis</u>

Types

Diagnosis is based on the Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV criteria (see Tables 3 & 4 of the original guideline document). The three main types are primary hyperactive, primary inattentive, and mixed.

Multiple Sources

No specific test can make the diagnosis. Input from both parents and teachers is required. Some psychological rating tools are useful (e.g., Vanderbilt, Connors; see Figure 1, Tables 1 & 2, and Appendix A1 of the original guideline document). Formal neuropsychiatric testing may be useful in certain situations.

Confused and Associated Conditions

Diagnosis is complicated by overlapping symptoms or co-occurrence of other disorders (e.g., anxiety disorders, bipolar disorder, fetal alcohol syndrome, major depressive disorders, learning disorders, oppositional defiant disorder, post traumatic stress disorder, reactive attachment disorder; see Appendices B1 & B2 of the original guideline document).

<u>Treatment</u>

Drug Treatment

- Stimulants are the first-line treatment and have proven benefit to most people. If one class of stimulant fails or has unacceptable side effects then another should be tried (see Tables 5-7 of the original guideline document)
- Atomoxetine (Strattera®) is a secondary choice. (One reported side effect is suicidal thinking.)
- Other medications may be used alone or in combination depending upon the ADHD type or with comorbidity profile: e.g., Alpha-II agonists (clonidine, guanfacine) with hyperactivity or impulsivity; bupropion (over age 8) with comorbid depression; risperidone (atypical antipsychotic) for aggression (see Table 8 of the original guideline document).
- Tricyclic antidepressants may rarely be used to treat ADHD; selective serotonin reuptake inhibitors (SSRIs) may be useful for depressive disorders. (There is a reported increase of suicidal ideation for SSRIs but SSRIs are not used to treat ADHD.)

Non-Pharmacologic Treatments

 Parental interventions: education and support, parent training class, family therapy (see Table 9 and Appendix A2 of the original guideline document)

- Behavioral interventions: routines and clear limits; positively reinforce target behaviors
- School interventions: consider evaluation for intelligence testing (IQ) and to rule out learning disorders. Affected children may qualify for special education services and an individualized education plan (IEP) (see Appendices A3 & A4 of the original guideline document).

Special Populations or Circumstances

Special considerations apply to 3- to 5-year-olds, adolescents, head-injured patients, mentally retarded/autistic patients, fetal alcohol syndrome, substance-abusing patients (see Appendix B3 of the original guideline document).

Controversial Areas

Common Myths

Several common beliefs related to ADHD are untrue (e.g., that it is not a real disorder, it is an over-diagnosed disorder, children with ADHD are over-medicated).

Diets

Although a few studies suggest dietary modification may have promise (e.g., individually tailored hypoallergenic diets, essential fatty acids, flax seed), studies have shown the Feingold diet and modifying sugar consumption have no effect.

Complementary Alternative Medicine

Use is controversial, but common (see Appendix B4 of the original guideline document).

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the diagnosis and evaluation of the child with attention-deficit/hyperactivity disorder.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of patients with suspected attention deficit hyperactivity disorder (ADHD)

POTENTIAL HARMS

Adverse effects of stimulants and non-stimulants used in treatment of attention deficit hyperactivity disorder are listed in Table 6 of the original guideline document. Drug class side effects for second-line drugs are listed in table 8 of the original guideline document.

CONTRAINDICATIONS

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Tricyclic antidepressants are contraindicated in children with cardiovascular disease or cardiac arrhythmias.

QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Staff Training/Competency Material

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Attention-deficit hyperactivity disorder. Ann Arbor (MI): University of Michigan Health System; 2005 Oct. 35 p. [8 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Oct

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUI DELI NE COMMITTEE

ADHD Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose personal financial relationships with commercial companies whose products or services are discussed. No member of the guideline team (Drs. O'Brien, Felt, Harrison, Kochhar, and Riolo) nor the consultant (Dr. Shehab) has such a relationship.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the <u>University of Michigan Health System Web site</u>.

PATIENT RESOURCES

The following are available:

- Attention-deficit hyperactivity disorder (ADHD). University of Michigan Health System; 2005 May. Various p. Electronic copies: Available from the <u>University</u> of <u>Michigan Health System Web site</u>.
- ADHD: what parents need to know. University of Michigan Health System;
 2005 Jul. Various p. Electronic copies: Available from the <u>University of Michigan Health System Web site</u>.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on December 8, 2005. The information was verified by the guideline developer on January 24, 2006. This summary was

updated by ECRI on August 28, 2006 following the updated U.S. Food and Drug Administration advisory on Adderall. This summary was updated by ECRI on September 7, 2006 following the updated U.S. Food and Drug Administration advisory on Dexedrine.

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